

Attorney Docket No.: **PENN-0795**
Inventors: **Clevenger and Kline**
Serial No.: **10/029,079**
Filing Date: **December 21, 2001**
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REMARKS

Claims 1-10 are pending in this application. Claims 6-10 have been withdrawn from consideration. Claims 1-4 have been rejected. Claims 2-3 and 6-10 have been canceled. Claim 1 has been amended. No new matter has been added by these amendments to the claims. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Restriction/Election

The Restriction Requirement placing claims 1-4 into Group I and claims 6-10 into Group II has been deemed proper and made Final. Accordingly, Applicants have canceled the non-elected claims, reserving the right to file continuing applications on the canceled subject matter.

II. Objection to the Claims

The claims have been objected to for failing to adhere to the requirements of sequence rules. The Examiner suggests that SEQ ID NO's must be appended to all mentions of specific sequences in the claims. Applicants have amended claim 1, and its dependent claims,

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to refer a specific sequence as requested. Withdrawal of this rejection is respectfully requested.

III. Rejection of Claims Under 35 U.S.C. 102(b)

Claims 1 and 2 have been rejected under 35 U.S.C. 102(b) as being anticipated by Mercado et al. (1994). The Examiner suggests that this reference discloses a human growth hormone/prolactin-binding protein in human milk. Applicants respectfully traverse this rejection.

At the outset, Applicants have amended claim 1 to refer to a recombinant human prolactin-binding protein of SEQ ID NO: 3. Support for this amendment can be found throughout the specification as filed. Mercado et al. (1994) disclose the existence of a putative human prolactin-binding protein in human milk samples. However, no sequence for this entity is provided. In fact, as is pointed out in the abstract, the size of this protein is less than the protein from serum and its identity is not definitively determined as "the precise nature and function of this protein remains to be elucidated". Clearly, this reference fails to teach or suggest the protein as now claimed, which has a defined sequence and is produced recombinantly. In order to anticipate an invention, the reference cited must teach each and every limitation

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of the claims (MPEP 2131). Clearly, this reference fails to teach the limitations of the amended claims. Withdrawal of this rejection is respectfully requested.

IV. Rejection of Claims Under 35 U.S.C. 103(a)

Claims 1-4 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Mercado et al. (1994). The Examiner suggests that this reference discloses a human prolactin-binding protein isolated from human milk and that it would have been obvious for one of ordinary skill in the art to make the recombinant form, comprising a pharmaceutically acceptable vehicle. Applicants respectfully traverse this rejection.

As discussed supra, Applicants have amended the claims to specify a particular human prolactin-binding protein sequence for the recombinant protein claimed. Mercado et al. (1994) disclose only the putative existence of such a protein in human milk samples, acknowledging that this protein's existence as definitive remains to be determined. Further, no sequence is given from which one of skill would deduce the sequence of SEQ ID NO: 3. It is only with the specification in hand that one has understood that the protein has the sequence as claimed.

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To establish a *prima facie* case of obviousness, three basic criteria must be met. MPEP 2143. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art must teach or suggest all claim limitations. A mere teaching of the concept of a human prolactin-binding protein existing in milk does not provide one of skill in the art with the understanding or an expectation of success that there would a specific protein with a specific sequence as claimed. It is only with the specification in hand that one of skill is able to see how to make such a human prolactin-binding protein of SEQ ID NO: 3. Further, only with the data in the specification as filed is it shown that the protein claimed is indeed a human prolactin-binding protein. In fact, the reference cited teaches that "the precise nature and function of this protein remain to be defined." The present invention has done just that. Therefore, this combination of art fails to establish a *prima facie* case of obviousness. Withdrawal of this rejection is therefore respectfully requested.

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V. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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